September 10, 2025

To Shareholders,

Company Name: Renascience Inc.
Representative: Toshio Miyata, Chairman and CEO
(Code: 4889 TSE Growth)
For inquiries, please contact Administration Dept.

Announcement of distribution of adjustment funds to accelerate practical application of the "Research on Development of new Medical Devices"

In collaboration with Tohoku University, several medical institutions such as St. Luke's International Hospital, NEC Corporation (NEC), NEC Solution Innovators Co., Ltd. (NES), and NIPRO CORPORATION, our company is developing a software as a medical device (SaMD) that utilizes artificial intelligence (AI) to support safe and secure maintenance hemodialysis. This project is being developed with the support of the "Research on Development of new Medical Devices Project" for fiscal year 2023 by the Japan Agency for Medical Research and Development (AMED) (the principal research institution is Tohoku University, and the principal Investigator is Professor Toshio Miyata). We are pleased to announce that we have received an additional distribution of 143,000,000 yen as adjustment funds to accelerate the practical application of this SaMD.

Approximately 350,000 patients with end-stage renal failure in Japan undergo hemodialysis three times a week to remove water and waste products in place of their depleted kidneys. In hemodialysis treatment, the most important medical issue is "appropriate water removal". Insufficient water removal impairs cardiopulmonary function, and excessive water removal causes hypotension during dialysis, leading to adverse events such as feeling unwell and loss of consciousness. This SaMD imitates and learns the target water removal volume set by dialysis specialists, and presents the target water removal volume to non-specialists and other less experienced doctors with the same accuracy as specialists.

Clinical performance test[1)] for regulatory approval of this SaMD was conducted from October 2024 as a multi-center collaborative clinical performance test at eight facilities (in different regions such as Tohoku, Kanto, Chubu, and Western Japan), including Tohoku University Hospital and St. Luke's International Hospital (the coordinating physician for the trial was Professor Tetsuhiro Tanaka, Department of Nephrology, Connective Tissue Diseases, and

Endocrinology at Tohoku University Hospital). The results of the clinical performance test (flash report) were disclosed on July 14, 2025 in "Clinical performance test (flash report) for regulatory approval of a SaMD using artificial intelligence (AI) to support maintenance hemodialysis." The average accuracy rate[2)] was 90.31 %, which significantly exceeded the initial target accuracy rate of 80% for the primary endpoint, proving the non-inferiority (equivalent) of the AI predictions to specialists[3)]. A promotional video for this SaMD, created with our joint research partner NIPRO CORPORATION, was released at the 70th Annual and General Meeting of the Japanese Society for Dialysis Therapy (June 27-29, 2025, Venue: Osaka International Convention Center).

Promotional video for this SaMD
(https://www.renascience.co.jp/wp-content/uploads/2025/06/video.mp4)

Since we have obtained Proof-of-Concept (proof of effectiveness)[4)] in the clinical performance test for regulatory approval of this SaMD, we will start developing the final application (system) to operate this SaMD in the medical field. We have received an additional 143,000,000 yen (adjustment fee) from AMED as research funds to accelerate the practical application of these.

At this time, this matter has no particular impact on our performance.

End

[1)] Clinical performance test
In order to develop a software as a medical device (SaMD) available for use in the medical field, it is necessary to verify whether the SaMD will perform as expected in the clinical field using actual human clinical data. Clinical performance test is a clinical study conducted for that verification. Based on the performance confirmed in the clinical performance test, we will apply to the Ministry of Health, Labor and Welfare to manufacture and sell it as a SaMD.

[2)] Correct answer rate
In consultation with the Pharmaceuticals and Medical Devices Agency (PMDA), the primary efficacy evaluation item was set as the correct answer rate (Correct rate) when the difference between the target water removal amount by this SaMD and the specialist is within the acceptable range. The acceptable range was set as the mean absolute error rate (MAPE) between the target water removal amount set by the specialist and the predicted water removal amount by this product is 12 % or less of the doctor-determined water removal amount (but the maximum is 300 mL).

[3] Proof of non-inferiority (equivalence) of this SaMD prediction to specialists

As a result of the clinical performance test, the obtained accuracy rate (average) was 90.31 %, which was significantly higher than the target accuracy rate of 80 % set as the primary evaluation item initially, proving the non-inferiority (equivalence) of AI prediction to specialists. The average amount of water removed in all dialysis cases in this study was 2,353 ml, and the mean absolute error (MAE) between the target amount of water removed set by the specialist and the predicted amount of water removed by this program medical device was 117.9 ml (<300 mL), which was within the range of about one cup. The subjects were maintenance hemodialysis patients attending multiple facilities in different geographical areas, such as Tohoku, Kanto, Chubu, and Western Japan, and all facilities showed high accuracy and precision.

[4] Proof-of-Concept (POC)

This refers to confirming the effectiveness of a new SaMD candidate through clinical trials, and if the expected results are obtained, it is said that POC has been obtained.